



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-23AP; Docket No. CDC-2022-0128]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a new proposed information collection project titled TRANSCEND: Transgender status-neutral community-to-clinic models to end the HIV epidemic. This project is designed to collect standardized program evaluation data from the clinics and community-based organizations who receive federal funds for HIV prevention and care activities.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0128 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each

proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

TRANSCEND: Transgender status-neutral community-to-clinic models to end the HIV epidemic - New - National Center for HIV, Viral

Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Transgender (TG) persons, especially transgender women (TGW), have a high prevalence of HIV and lifetime risk of acquiring HIV. In the 2019-2020 National HIV Behavioral Surveillance Trans cycle, 42% of TGW tested positive for HIV. Racial/ethnic disparities were also found, with HIV positivity rates of 62% among Black/African American TGW and 35% among Hispanic/Latina TGW compared to 17% among White TGW. Despite the disproportionate burden of HIV among TGW, receipt of HIV prevention and care services have been suboptimal. Among TG persons, 92% reported that they were aware of pre-exposure prophylaxis (PrEP) but only 32% had used it. In 2019, viral suppression among persons with diagnosed HIV was 67% among TGW. Large proportions of TG persons experience poverty, homelessness, abuse, and have substance use or mental health disorders, which impact access to and utilization of HIV prevention and care services. Many TG persons seek gender-affirming care, including hormone therapy, at transgender healthcare organizations (TG clinics), and these encounters provide opportunities for HIV testing and status-neutral HIV services.

In the proposed demonstration project, TG clinics and transgender-serving community-based organizations (CBOs) will work collaboratively to develop and evaluate community-to-clinic

models to provide integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary healthcare, as well as to ensure access to mental health, substance use, and social support services. All services will be culturally and linguistically responsive for TG persons to ensure that they feel welcomed, heard, and cared for. The recipients will also participate in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide status-neutral, community-to-clinic services for TG persons.

This collection of deidentified data will allow CDC to assist TG clinics and CBOs in monitoring and evaluating their programs and to identify best practices for providing status-neutral HIV services and comprehensive healthcare for TG persons and for community-to-clinic models of service provision. Longitudinal person-level data collection will occur through the clinic's electronic health record (EHR) and a database shared between clinic and CBOs, and additional program evaluation data will be collected through client surveys.

CDC requests OMB approval for an estimated 329 annual burden hours for the recipients to collect, enter or upload, and report client demographic and behavioral characteristics, client data from the EHR, and client surveys. There are no other costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)
TRANSCEND Recipient Data Manager	Electronic Health Record Data Form	4	2	8	64
TRANSCEND Recipient Data Manager	Client Info Form	4	2	2	16
TRANSCEND Clients	Client Info Form	1000	1	5/60	83
TRANSCEND CBO Staff	Client Info Form	8	100	5/60	67
TRANSCEND Clients	Client Program Evaluation Survey	1000	1	5/60	83
TRANSCEND Recipient Data Manager	Client Program Evaluation Survey	4	2	2	16
Total					329

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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